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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,339	01/26/2004	Shawn R. Feaster	034047.003DIV1 (W 00-23B)	7108
53502 7590 09/09/2009 OFFICE OF THE STAFF JUDGE ADVOCATE (SKS) U.S. ARMY MED. RESEARCH & MATERIEL COMMAND 504 SCOTT STREET ATTN: MCMR-ZA-J (MS. ELIZABETH ARWINE) FORT DETRICK, MD 21702-5012			EXAMINER SHEN, BIN	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 09/09/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Status of the Claims

Claims 29-36 and 39 have been presented for examination.

Claims 31-34 and 36 remain FINALLY withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 31 May 2006. Claims 29, 30, 35 and 39 are examined on the merits.

This application contains claims 31-34, 36 drawn to an invention nonelected with traverse on 5/31/2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

New Ground of Rejection Necessitated by amendment:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29, 30, 35, 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, at the time the invention was made, of the specific subject matter claimed.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention*. Disclosure of any

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combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

In the instant case, claim 29 refers to “adding means”, “measuring means”, and "software means", however it is unclear what structures correspond to the newly recited “means” since it was not described in the specification in such a way as to reasonably to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The words “adding”, “measuring”, and “software” appear several times in the specification, however, no specific structures (such as tools to add/measure) are associated with the specific “means”. Software is not a structure. Thus, the specification does not provide support for the claim. One skilled in the art would conclude that the inventors were not in possession of the claimed invention since it is not clear if they were in possession of a device for detecting, measuring or monitoring the activities or concentrations of protein in a sample. Thus, the claims fail to comply with the written description requirement.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Maintenance of Rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 29-30, 35, 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 29, the word "means" is preceded by the word(s) "determining" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967). The phrase "means for" is modified by some structure recited in the claim (lines 7-21), but it is unclear whether the recited structure is sufficient for performing the claimed determining function. Applicant is required to clarify whether the limitation is invoking 112, 6th paragraph.

Since it is unclear the recited structure in the claim would preclude application of 112, 6th paragraph, the prior art rejection is applied until the applicant clarifies whether the limitation is invoking 112, 6th paragraph.

Applicant's arguments filed 7/2/2009 have been fully considered but they are not persuasive.

Applicant argues that claim 29 have been amended to clarify the device contains software means to calculate sensitivity coefficients based on measured reaction rates.

It is the examiner's position that the present invention claims a device with means for adding/measuring/determining, however the "means for" are not modified by sufficient structure, material, or acts for achieving the specified function, thus it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967). The specification does not provide any description of structures correspond to the newly recited means (such as software means), thus the amended claims do not meet 112-1st (see the new ground of rejection above). Software is not structure.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorette et al. (Applied Biochemistry and Biotechnology 1998; 74:1-12).

Dorette et al. teach an enzyme biosensor (read as a device; page 12) for the determination (read as detecting/measuring) of cholinesterase on polymer membrane (see abstract). The biosensor teaches means to add (same function as a sealed chamber, see page 2, line 11-14) the plurality of substrates to a plurality of aliquots of the test sample (read as means for adding substrates to test sample), and means to detect/measure activities/concentrations of different substrates (read on as measuring reaction rates, see page 2, 7th paragraph) by measuring the reaction rates amperometrically (see Fig. 1, Fig. 3 and Table 1).

Additionally, the claimed device in claim 29 read on as a spectrophotometer see page 5, 3rd full paragraph which comprises a means for adding substrates (the cover), a means for measuring reaction rates (the optics and photodetector) and means for determining the activity (the output of the spectrophotometer to a strip chart or data collection means).

The functional intended use with diluting, calculating and extracting sensitivity coefficients does not materially change the device and accordingly is given no patentable weight. That is the device is the same whether these activities are practiced or not. The device can be used in alternative measurements, particularly the spectrophotometer which can be used to obtain a spectrum of other molecules.

Therefore, the cited reference is deemed to anticipate the instant claims above.

Applicant's arguments filed 7/2/2009 have been fully considered but they are not persuasive.

Applicant argues that the device of Dorette does not teach or suggest the claimed invention because the device is not capable of measuring a protein or a plurality of proteins in a sample.

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It is the examiner's position that the present invention claims a device with means for adding/measuring/determining, however the "means for" are not modified by sufficient structure, material, or acts for achieving the specified function, thus it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967). Doretto's teaching of measuring reaction rates is considered "equivalents" until applicant clarify the "means for" steps with sufficient structure/material/acts for achieving the specified function. The equations to calculate sensitivity coefficient is not described in the specification as part of the structure of the software means.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29, 30, 35, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doretto et al. in view of Magnotti et al. (Clinica Chimica Acta, 1988;315:315-332), and further in view of Ellman et al. (Biochemical Pharmacology 1961;7:88-95).

Doretto et al. teach what is above.

Doretto et al. do not explicitly teach use of the sensor in a handheld device with a cartridge.

Magnotti et al. teach the reagents (see pages 317-318) needed for the testing device and the advantages to develop a portable and convenient device/kit (read on as handheld) with stable, premixed reagents (read on as cartridge) to measure cholinesterases in a field assay (see abstract and also page 329, 3rd full paragraph) because field monitoring erythrocyte and plasma cholinesterase activities is beneficial to agricultural workers and others at risk for pesticide exposure (see page 331, 2nd full paragraph).

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Ellman et al. teach a new and rapid colorimetric determination of acetylcholinesterase activity which is later developed into the Test-Mate OP kit by EQM Research Inc., Cincinnati, OH, USA (as stated on page 1078, lines 11-14 of Paz-y-Mino et al. Environmental Health Perspectives 2002;110:(1077-1080)).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to develop a handheld device with a biosensor (as taught by Dorette et al.) and a cartridge (whose convenience is suggested by Magnotti et al.) to monitor enzyme activity because Dorette et al. teach a biosensor to detect enzyme activity, and Magnotti et al. teach the reagents that are needed for the enzyme assay and suggest to develop a portable and convenient device to monitor cholinesterases activity in the field. One would have been motivated to make the modification because Magnotti define the optimal criteria for field measurement of cholinesterase (see page 328, 1st paragraph of Discussion) and the need for a portable/handheld device/kit with stable, premixed reagents (cartridge), and would reasonably have expected success because Dorette et al. teach how to make a biosensor for cholinesterase detection, and Magnotti et al. teach many advantages of developing a portable, convenient and stable assay system to be used in the field.

The Test-Mate OP system has all the components that are required for the detection of cholinesterase as described by Ellman et al., thus it would have been obvious to one of ordinary skill in the art to use the Test-Mate OP kit to detect, measure or monitor the activities or concentrations of cholinesterase instead of the claimed device.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed 7/2/2009 have been fully considered but they are not persuasive.

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Applicant argues that the device of Dorette does not teach or suggest the claimed invention because the device is not capable of measuring a protein or a plurality of proteins in a sample.

It is the examiner's position that the present invention claims a device with means for adding/measuring/determining, however the "means for" are not modified by sufficient structure, material, or acts for achieving the specified function, thus it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967). Dorette's teaching of measuring reaction rates is considered "equivalents" until applicant clarify the "means for" step with sufficient structure/material/acts for achieving the specified function. Specific structure components are required to be recited in the specification to provide sufficient support for "adding means", "measuring means", and "software means".

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If

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Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571) 272-0925.

/Bin Shen/

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/Karen Cochrane Carlson/

Primary Examiner, Art Unit 1656